Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 18 **/ 2025**

29 -07-1446 H
29 -01-2025

Field Safety Notice of ROTEM sigma complete & ROTEM sigma complete + hep from Tem Innovations GmbH (Werfen).

Source	SFDA- Saudi Food & Drug Authority https://ade.sfda.gov.sa/Fsca/PublishDetails/250
Product	ROTEM sigma complete & ROTEM sigma complete + hep.
Manufacturer	Tem Innovations GmbH (Werfen).
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	ROTEM sigma complete. - Part No.: 555501 - Lot No.: S221203 ROTEM sigma complete + hep. - Part No.: 555502 - Lot No.: S221204 Exp. Date (YYYY-MM-DD): 2024-06-30.
Reason	The FIBTEM C A5 results obtained with the current IVDR version exhibited a bias from measurements made with the previous IVDD version for a population within the Obstetric setting, leading to an adjustment in a bleeding management algorithm.
Action	The manufacturer instructs the customers to follow these actions: 1. Check if you have established a bleeding management algorithm for ROTEM sigma, 2. If yes, verify the established bleeding management algorithm for a potential impact due to the bias between the IVDD and the IVDR cartridges and take appropriate validation actions for your algorithm following your internal procedures. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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سلطنة عُمان
وزارة الصحة
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مسقط

نتقدم بثقة
Moving Forward with Confidence

رؤية عُمان 2040

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 18/2025 **dated** 29/11/2025 **Regarding SFDA Field Safety Notice of ROTEM sigma complete & ROTEM sigma complete + hep from (mfr:Tem Innovations GmbH (Werfen)).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ISO 9001:2015 CERTIFIED

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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

werfen

URGENT FIELD SAFETY NOTICE
ROTEM® *sigma* complete Part No. 555501
ROTEM® *sigma* complete + hep Part No. 555502

November 15, 2024

Dear Valued Customer:

This notification is intended to advise your facility regarding a performance issue identified with ROTEM *sigma* complete and ROTEM *sigma* complete + hep product lot numbers starting with the letter "S" + 5-digit number from 221203 (ROTEM *sigma* complete) resp. 221204 (ROTEM *sigma* complete + hep). The table below identifies the initial LOT number per product.

Product Name	Part No.	Lot No.	Exp. Date(YYYY-MM-DD)
ROTEM sigma complete	555501	S221203	2024-06-30
ROTEM sigma complete + hep	555502	S221204	2024-06-30

- **Issue Description and Impact**

It has come to our attention through a customer complaint, that the FIBTEM C A5 results obtained with the current IVDR version exhibited a bias from measurements made with the previous IVDD version for a population within the Obstetric setting, leading to an adjustment in a bleeding management algorithm.

- **Mandatory Customer Actions**

Based on the above, please take the following **immediate** actions:

- **Check** if you have established a bleeding management algorithm for ROTEM sigma
- **If yes, verify** the established bleeding management algorithm for a potential impact due to the bias between the IVDD and the IVDR cartridges and take appropriate validation actions for your algorithm following your internal procedures.
- **Document** the acknowledgement on the Customer Reply Form and **return** the completed and signed form to the fax number or e-mail address listed on the next page.
- **Share** this information with your laboratory staff and follow your internal procedures.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification for your records.

- **Customer Reply Form**

The customer reply form can be communicated to Werfen via the below options:
- e-mail address: tem-ra@werfen.com
- Fax no.: + 49-89-45429522

- **Contact information for questions**
  - For technical questions please contact your local Werfen representative

We appreciate your prompt attention to this Urgent Field Safety Notice Letter.
Sincerely,

Signed by David Jacob
David Jacob | I approve this document | 11/15/2024 | 3:52:00 PM CET
580C197BCA4643899FB4C4DDA06F4347

David Jacob

Director of Quality Assurance and Regulatory Affairs, PBM
PRRC
Tem Innovations GmbH